UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456** C.A. No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL ACTIONS	Judge Patti B. Saris

CERTAIN NAMED PLAINTIFFS' OBJECTIONS TO PLAINTIFFS' SUPPLEMENTAL SUBMISSION IN SUPPORT OF REBALANCED TRACK TWO SETTLEMENT

I. INTRODUCTION.

Certain Named Plaintiffs hereby object to Class Counsel's "Supplemental Submission in support of a Rebalanced Track Two Settlement" ("Supp'l Submission"), for the brief reasons that follow, which merely supplement the reasons previously given in their objection papers and at the previous Fairness Hearings.

The proposed Track Two settlement is broken beyond repair. What should be painfully clear to the Court at this point is that Class Counsel have done an awful job of protecting consumer interests in this the self described "most complicated settlement…, even by AWP standards". July 7, 2011 Hrg. Tr. 66:6-7. Back in 2008, Class Counsel chose to "arm"[1] consumers with advocates in the allocation with TPPs whom they knew (or should have known) would do nothing more than rubber stamp the recommendations of Class Counsel. That they were mere "toys" of Class Counsel is shown by their complete absence from these proceedings –

[1] *See Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 621 (1997)("[I]f a fairness inquiry under Rule 23(e) controlled certification, eclipsing Rule 23(a) and (b), and permitting class designation despite the impossibility of litigation, both class counsel and court *would be disarmed*. Class counsel confined to settlement negotiations could not use the threat of litigation to press for a better offer…")(Emphasis added).

now, at their most critical juncture. Indeed, seeing the deal they brokered slipping away, Class Counsel simply jettisoned these supposed "consumer advocates" and took it upon themselves to "contact() TPP counsel" – they don't say who or when – and garnered an agreement "to increase the consumer allocation by an additional $3,125,000." Berman Decl., Dkt. No. 7703 at ¶ 103. To that we say, imagine what could be done if someone truly empowered to fight for consumers' best interests were permitted to do so in this case.[2] To try to bring that leverage to the consumer cause in this case, Certain Named Plaintiffs are filing contemporaneously herewith a Motion for Leave to Intervene, which, if granted, might allow Defendants to obtain the broader release they seek for the Newly-Added Drugs under their own cited precedent. *See City Partnership Co. v. Atlantic Ltd. Partnership*, 100 F.3d 1041 (1st Cir. 1996)(permitting a class release to be expanded upon proper showing that, *inter alia*, there was adequate discovery of the newly-added claims and adequate protection of the class of persons being added, through intervention and involvement in the settlement negotiations.)

The current 80/20 split between TPPs and consumers is as arbitrary as the 82.5/17.5 split that preceded it.[3] It just looks better. So, Class Counsel hope the Court will simply look at the

[2] In a footnote of their Brief, Class Counsel report that "[u]nfortunately, mediation efforts with Don Haviland have not yet resulted in the resolution of the Haviland objections." Dkt. No. 7697 at 2 n. 2. Cognizant of this Court's Order dated July 7, 2011 for the undersigned attempt to mediate, an Affidavit will be prepared for submission to the Court at the hearing, for its *in camera* review, explaining the reasons why the mediation effort failed. For purposes of the instant objections, however, suffice it to say that adequate structural protections for the mediation, as mandated by *Amchem*, were not agreed to by Class Counsel, and no demand of the TPPs was ever made by Certain Named Plaintiffs. Despite this lack of a demand, TPPs were willing to give up $3.125 million, evidencing their fear of the strength of the consumers' case and the merits of the pending objections to the proposed settlement and allocation.

[3] It is noteworthy that Mr. Berman first represented to this Court that "[t]he consumer allocation … was driven in large part, the 82/17 split, by Dr. Hartman's utilization numbers. It was based in scientific study." June 13, 2011 Hrg. Tr. at 66:18-21. Nowhere does he make such representation as to the new 80/20 split. So, rather than abandon such "scientific study" in favor

deal in that way, refusing to probe beneath the surface to examine the serious structural problems the many machinations of Class Counsel belie. The Supreme Court has admonished this Court to not turn a blind eye to this "blinded" settlement. When serious structural problems are uncovered, they must be addressed and resolved. *See Amchem supra*. Otherwise, structural weakness in the constitutionally mandated adequate representation of consumer interests may undermine the very foundation of the proposed settlement and settlement class.

Unfortunately, in its understandable haste to push this broken settlement to some final resolution, this Court has unfairly handcuffed Certain Named Plaintiffs. Forty-eight hours is hardly enough time to examine hundreds of pages of documents from Class Counsel, Track 2 Defendants, Dr. Hartman, Class Representatives and others all dumped into the record in wild, finish-line dash for support. Twenty pages is hardly enough space to address the varying contentions scattered across the proponents' submissions. The "very cogent" objections this Court remarked that Certain Named Plaintiff have interposed to the proposed settlement and allocation -- which were hoped to have become a catalyst for change and improvement – have only spurred of flood of paper supporting token moves. July 7, 2011 Hrg. Tr. at 23:15-21.

In these few pages, Certain Named Plaintiffs will try one last time to refocus the Court and the parties on what should be most important at this juncture in this proposed class action:

---

of arbitrary percentage choices – like the move to 80/20 from 82/17, Certain Named Plaintiffs suggest that the Court order the reallocation between consumer and TPPs be done according to their application of Dr. Hartman's recent "scientific study" which yields overcharge damages well in excess of his 30% "speed limit" for dozens of Group B drugs. The brands should be treated as Group A drugs, and the multi-source drugs can remain in Group B, but with damage-based settlement payouts instead of arbitrary percentages [like the move from 5% to 15%]. *See generally,* Affidavit of Michael J. Lorusso at Exhibit "B" hereto (examining Dr. Hartman's recent overcharge damage tables and calculating proper damage amounts based upon existing claims).

protecting the rights of those who have greatest need of the class action device to achieve a fair, reasonable and adequate resolution of their Track 2 claims.

II. OBJECTIONS TO THE PROPOSED "REBALANCED TRACK TWO SETTLEMENT".[4]

1. The Consumer Allocation Remains Woefully Insufficient to Compensate Consumers for Their Damages for Either the Original "Subject Drugs" or the "Newly-Added Drugs".

The flood of recent paper should not deviate the Court from its earliest, cogent observation when the issue of settling the Newly-Added Drugs was first raised: "we shouldn't be releasing drugs that weren't subject to litigation." June 13, 2011 Hrg. Tr. 67:25-68:2. In their previous filings,[5] Certain Named Plaintiffs pointed out how approximately 85 drugs were added to the Track 2 settlement release – drugs that had been previously stricken from the case when they were added by amended complaint. In their respective filings, both Class Counsel and Defendants take great pains to point out the fact that in 2 proposed amended complaints – the fourth and fifth – Class Counsel added in many, if not all, of these drugs. But twice Defendants moved to have them stricken from the case and twice this Court granted this request. Remarkably, the settling parties fail to proffer any legal argument in support of their actions. In their prior pleadings of record, *see supra*. n. 1, Certain Named Plaintiffs explained how these drugs were stricken. In response, both Class Counsel and Defendants focus on their appearance in pleadings – despite this Court's Orders striking such amendment to pleadings.

Under *City Partnership*, which Defendants rely upon for the admitted expansion of the scope of the release, they must demonstrate that adequate discovery was conducted. Below, we

[4] Since this Court limited the parties to interposing objections only to the proposed reallocation, prior objections to the proposed settlement and settlement classes will not be repeated here.

[5] *See* Response to Track Two Defendants' Memorandum in Support of Track Two Class Action Settlement, filed July 5, 2011, and Certain Named Plaintiffs' Objections to Class Counsel's Proposal to Redistribute the Track Tow Consumer Allocation, filed July 6, 2011.

demonstrate that the discovery, if any, as to Newly Added Drugs was anecdotal, at best. Nowhere does Class Counsel or defense *demonstrate* that these drugs were the subject of vigorous discovery such as would inform the plaintiffs as to the merits of the claims for these drugs.

But, aside from whether they may be permitted to expand the scope of the release – to which Certain Named Plaintiffs continue to object – the fact remains that these drugs were an afterthought in the settlement negotiations. Dr. Hartman does not attest that he ever examined spreads for these drugs in the context of settlement negotiations. Instead, his recent Declaration attempts to do so relying upon admittedly limited data sets: wholesaler and ASP data. However, wholesaler data is not relevant to direct-to-physician sales of the branded cancer agents in the Group B drug list which most concern Certain Named Plaintiffs. While Dr. Hartman has examined this limited data, and calculated overcharge damages for some, but not all, of these drugs, the body of his work is incomplete.

But, in the interest of trying to move the ball on settlement, Certain Named Plaintiffs have worked with their own experts and tried to present a model for damages, and a template for examining reallocation with the TPPs, using Dr. Hartman's "scientific study". *See* Affidavit of Michael J. Lorusso ("Lorusso Decl.") at **Exhibit "A" hereto** [and exhibits thereto]. Class Counsel submitted the first Declaration by Dr. Hartman in the Track 2 settlement,[6] wherein Dr. Hartman "summarize[d] certain calculations [he] made in support of the settlement with the Track 2 Defendants and the allocation of that settlement." Dkt. No. 7699. Therein, Dr. Hartman provided the specific overcharge ratios he calculated that were then used to calculate the damage-based payment for "Group A" drugs. Dr. Hartman also provided the same for a "subset"

[6] It is significant that in 2006 Dr. Hartman previously calculated spreads for many Track 2 drugs, but now claims that it is not possible to do so. *See* **Exhibit "B" hereto** (filed under seal).

of "Group B drugs."[7] Because Dr. Hartman was able to calculate specific overcharge ratios for this subset of Group B drugs, Certain Named Plaintiffs maintain that payments for those claims (as well as all other claims once Dr. Hartman provides such information) should be based on actual damages, as opposed to the arbitrary pro rata distribution currently espoused by Class Counsel.

Looking only at those drugs properly included as Group B drugs that Dr. Hartman provided an overcharge ratio and/or those drugs that Dr. Hartman provided a reasonable proxy for the same as discussed in the Lorusso Declaration, and calculating the damage-based payment for those claims, **consumer Class members would receive an additional $3,168,865.37 if the payments were damage-based as opposed to the proposed 14.087% pro rata**. *See* Lorusso Decl. at ¶¶ 3-8.

As discussed above, Certain Named Plaintiffs maintain that those drugs Class Counsel and Defendants now concede are single-source, branded injectables all should be included in Group A. We contend Class members should receive double their damages for those claims. Applying such a damage-based model to the payment of those claims, using the Dr. Hartman provided overcharge ratios and/or a reasonable proxy for the same, C**lass members would receive an additional $44,628,632.72 versus using the proposed 14.087% pro rata distribution**. *See* Lorusso Decl. at ¶¶ 9-15.

Lastly, **there are twenty-three (23) additional drugs that Certain Named Plaintiffs**

[7] Dr. Hartman's claim that the subset was "was determined either by data availability or by requests by counsel" is belied by the fact that even for some drugs included in Table 2 to his Declaration he indicates that overcharge ratios are "'not available' because no data were received for this drug." Hartman Declaration at 28 of 49; *see also*, Exhibit "B" hereto. If the specific drugs analyzed were determined by data availability, as opposed to by requests by Class Counsel, then presumably Dr. Hartman would not have included those drugs where the data was unavailable in his chart. *See* Hartman Declaration at Table 2 (regarding Bebulin, Buminate, Dexamethasone Sodium, Fluorouracil, Gentamycin Sulfate, and Lyphocin).

maintain should be included as "Group A" drugs, but are currently listed as "Group B" drugs. *See* Lorusso Decl. at ¶16 and Exhibit "E" thereto. Applying a damage-based model to the payment of those claims, using the Dr. Hartman-supplied overcharge ratios and/or a reasonable proxy for the same, and providing double damages to the same as Class Counsel propose for Group A drugs, **Class members would receive an additional $8,433,084.79 versus using the proposed 14.087% pro rata distribution**. *See* Lorusso Decl. at ¶¶ 16-21.

In the aggregate, if payments were made based on estimated damages (which is what Class Counsel propose), as opposed to the pro rata distribution of 14.087%, and the same was doubled for those drugs that should properly be part of "Group A", as reflected in Exhibits "B" through "D", **the consumer Class would receive $56,230,582.88 in additional payments.**[8]

Apart from the fact that the consumer allocation remains too low, and the product of tainted, inadequate representation, too many variables exist for this Court to decide at this juncture whether the current proposed allocation to consumers is fair, reasonable or adequate. For instance, Class Counsel concede "[i]t is difficult to predict with any certainty the amount of 'not otherwise classified' drug claims that will result" from their proposed change, *i.e.*, to strip away $5.1 million in Total Recognized Claims and reallocate it to the larger Group B settlement

[8] Class Counsel have accused counsel for Certain Named Plaintiffs of not coming forward with their own expert reports to establish the value of the claims for Newly Added Drugs. While it is not incumbent upon objectors to do so, to establish a record of the value of the Eligard and Trelstar claims, the Court should examine the expert reports of the undersigned's experts (Dr. Schondelmeyer and Econ One) in the *Lupron* cases in New Jersey (*Walker*) and North Carolina (*Stetser*). *See* **Exhibits "C" and "D"** hereto, respectively. Dr. Hartman also provided an analysis of Lupron damages in MDL 1430. *See* **Exhibit "E"** hereto. As for liability and damages for Pharmacia Track 2 drugs, beyond the Wisconsin verdict previously cited, e refer the Court to the expert economist reports of Dr. William S. Comanor and Dr. Rick Warren-Boulton at **Exhibits "F" and "G"**, respectively. The experts have twice been accepted by the Pennsylvania court as qualified to render opinions on AWP spreads and damages. *See* BMS Verdict at **Exhibit "H"** hereto, J&J Verdict at **Exhibit "I"** hereto.

pool. Dkt No 7607 at 17. Without knowing what consumers can make out the new proofs required of them – should they be approved by the Court – the amount of dollars available to Group B drug purchasers will remain unknown. Class Counsel conceded that the number will surely go down as some consumers will be able to make out such showing. *See id*. (speculating that claims will drop "to less than $500,000.00")

Another major variable in the amount of funds available for individual consumer payouts is the number of additional claims that would come in if the Court would order first class mail notice to be sent to all identifiable Class members – especially those whom the parties concede purchased branded, single source drugs that should have warranted their inclusion in Group A. If the claims response rate of Group A consumers is any measure, the claims for Group B drugs will go up substantially, thereby diluting the remaining Group B settlement pool.

For these reasons, if the settlement is to be salvaged, consumers need zealous, unconflicted advocates challenging the TPPs and getting what they deserve based upon their unquestionably stronger claims and a realistic valuation of them. One sword Certain Named Plaintiffs would seek to wield is the fact that the case law does not permit TPP class members to opt in and out of class actions, depending on the success of the case against individual defendants.

Class Counsel has not explained the justification for the decision of TPP allocation counsel to simply hand over $3,125,000 to the consumer Class, nor have they explained how the parties arrived at the seemingly arbitrary amount.[9] Certain Named Plaintiffs object to any TPP

[9] The original settlement provided that Consumers would be awarded 17.5% of the settlement fund with TPP Class Members and the ISHP's each receiving 41.25% of the fund. The proposed

opting out of this proposed settlement Class and participating in this settlement as part of the ISHP group if that TPP had not previously opted out as part of the litigation class certification and/or the very first settlement with GlaxoSmithKline. It is improper to allow class members to sit on the sideline and pick and choose which settlement(s) in the same overarching litigation they would like to participate in. *See Martens v. Smith Barney*, 190 F.R.D. 134, 139 (S.D.N.Y. 1999) ("[N]o precedent exists for permitting class members to opt out of a class, whether certified for purposes of settlement or otherwise, with respect to some defendants or claims but not others.") (*citing In re Del-Val Financial Corp. Securities Litig.*, 162 F.R.D. 271, 276 (S.D.N.Y. 1995).

Here, the amount of money available to consumers hinges on the split between the consumer and TPP classes. We cannot allow the ISHPs to raid the Class funds, drawing to them more claimants for their purported "private settlement", because it reduces the ability of the consumers to negotiate a reasonable split with the TPP class. The Court need look no further than the ISHP list to see that the certified named Class representatives for Class 2 TPPs in Track 1, BCBS of Massachusetts, now looks to opt out of its own case and share in the mysterious spoils of the private ISHP settlement. Having gone to trial in this case, and had its rights adjudicated, BC/BS Massachusetts cannot abandon the TPP Class, taking with it some allocated share of the TPP Class settlement proceeds.

2. Track 2 Defendants' Should be Estopped from Denying Certain Drugs Are Branded PADs and that They Produced Discovery After Prevailing on Their Objections to Doing So.

---

reallocation does not specify the allocation between ISHP and TPP members of the 80% now earmarked for the total TPPs. In other words, who is paying the additional $3.125 million?

Importantly, Defendants have not even done what this Court ordered. At the July 7, 2011 hearing, the Court instructed the Track Two Defendants to submit briefing detailing each Defendant's evaluation of their liability exposure to their drugs within the 85 drugs being added to the proposed settlement. Specifically, the Court wanted each Defendant (and the Defendants collectively) remove the "blind box" and to answer for the Court: "Who contributed what? What was your exposure? How much exposure was there in the release drugs?" July 7, 2011 Hrg. Tr. at 52:14-23. The Court said "I'll need briefs and affidavits from everybody or one collective one." *Id.* The Court's expectations were consistent with an earlier exchange with counsel for Baxter, with the Court stating "So you're going to have to show me why it's fair. I need those filings from the defendants too; how you've done your valuations, why this is fair." *Id* at 33:3-6. The Defendants have filed one, collective memorandum in response the Court's instructions – which fails to respond to the core issues.

The Defendants' Memorandum is devoid of the details the Court requested: there is no risk analysis, no liability evaluation, either by drug or in the aggregate, and no removal of the "blind box", specifically advising the Court "why this is fair" based upon individual Defendant valuations and "who contributed what". The Defendants simply thumb their noses at these important issues.

While they do concede that twenty-two (22) of the drugs are branded, single source drugs, Defts' Mem. at 9, they do not concede that they belong within the "Group A" drugs. At a minimum, the Court should expect the Defendants to evaluate the liability and risks attendant to each of these 22 drugs. Defendants are silent. Consequently, the Court has no basis for evaluating why Aventis agreed to have a brand drug like Anzemet included as a Group A drug [with higher consumer damage payouts], yet allowed their Lupron-like drug Eligard – with

nearly $3 million in claims – to be lumped within the Group B drugs. Had Aventis done what he Court required, it would have had to concede that it did no analysis of the risk of liability for Eligard because there was no such risk at the time Class Counsel settled. Class Counsel never sought or received any Eligard discovery and thus had no clue that they were simply giving away a valuable claim against Aventis for nothing[10] – the same claim they settled in Judge Stearns court for $150 million.

Defendants articulate an irrelevant "standard" to try to justify including some of these 22 branded, single source drugs as Group B drugs, rather than Group A drugs: that ten (10) of the drugs generated claims less than $50,000[11]. As the Court well knows, the volume of settlement claim dollars has never been part of what the settling parties describe as the "three pronged test" used to determine liability exposure. And, as discussed elsewhere, the fact that claim volumes are low on branded single source drugs is a function of the settling parties' refusal to send the consumers of these drugs first class mail notice, as they did consumers of Class A drugs where volumes were predictably higher. Importantly, by singling out 10 of 22 drugs, Defendants ignore the remaining 12 branded, single source drugs which they must concede had claim volumes in excess of $50,000, presumably thereby warranting their inclusion as Group A drugs.

[10] Perhaps one reason Class Counsel were unaware of what they were giving up lies in the fact that they believed they were settling with Aventis Pharmaceuticals, the Defendant they sued. Yet, in the negotiation of the Settlement Agreement and release, Aventis's counsel obviously prevailed in getting Class Counsel to release claims against "Sanofi-Aventis", the parent of Aventis and the maker of Eligard, as well as Aventis Behring and ZLB Behring. Certain Named Plaintiffs simply remind the Court of their outstanding objections to the inclusion in the settlement release of companies who were never sued, companies like Sanofi, G.D.Searle, and CSL Behring.

[11] Inexplicably, despite the Court's explicit directive, Defendants do not provide any identification of these 10 branded, single source drugs in their Memo or attachments thereto. Nor is there any list of the 12 drugs that presumably had claim volumes over $50,000.

This Court was assured by defense counsel at the close of the July 7th Hearing that "[o]ne other thing your Honor – Jim Muehlberger for Aventis – I want to make clear on the record today, **we will provide you with the information you have requested**…." July 7, 2011 Hrg Tr. at 66:17-20. Their refusal to do so should be cause to strike their submission as non-responsive, and deem admitted their concession that 22 drugs in Group B are in fact branded, single source drugs – as Certain Named Plaintiffs contended – and should be treated as part of Group A for payment of double damages.

Class Counsel and counsel for each individual Defendants have submitted carefully crafted affidavits in an effort to appease this Court's concerns as to the adequacy of drug-specific discovery conducted in this case, and in particular, with regard to the 85 new drugs recently added. Clearly counsels' primary focus is to cite to volumes of pages produced, in support of their general notion that sheer volume equates to thorough, properly targeted, and fulsome discovery; it does not.[12] Furthermore, the declarations prepared and signed by the individual Defendants' counsel wherein they make broad, sweeping assertions that all "Exhibit B" Drugs were subject to discovery in these proceedings are simply false.

Defendants made these same overly broad assertions in the Pennsylvania AWP case, and they were rejected by the Court. In so ruling, the Pennsylvania Court rejected sworn affidavits stating that all subject drugs had been reasonably searched. The Court entered an Order, dated December 21, 2009, directing that discovery be produced by Defendants, "concerning those drugs named in the appendices to the Commonwealth's Motion to Compel that are the subject of

[12] Perhaps of some relevance is that while counsel tout production of millions of pages in some instances, they just as emphatically tout the supposed adequacy of 58,000 pages (Watson, although Class Counsel attests to 83,000 pages), 70,000 pages (Sicor, although Class Counsel attests to 167,000 pages) and those of Fujisawa (100,000), Pharmacia (140,000) and Aventis (233,000). If volume is relevant, these Defendants certainly fail their own test.

claims based on 'marketing the spread' or 'other inducements,' and that were not targeted for search in the MDL (multidistrict litigation in federal court), and for which discovery has not previously been provided in any other legal action." *See* December 21, 2009 Order at **Exhibit "J"** hereto.

Interestingly, one of those very drugs "not targeted for search" in the MDL proceedings at the time Pennsylvania sought discovery, and that was subject to search and production in accord with the December 21, 2009 Order, is Azmacort, a drug manufactured by Aventis, and a Newly Added Drug in this case. As here, Aventis's counsel claimed that they had done an adequate search in the MDL for all drugs in Pennsylvania (*See* October 13, 2009 Affidavit of Jennifer McGee at **Exhibit "K"** hereto), and that all Aventis drugs identified have been "subject to some form of discovery" having produced "numerous disks of transactional data and more than a quarter million pages of responsive documents." *See* Declaration of Michael L. Koon, August 3, 2011 at **Exhibit "L"** hereto. Aventis seeks to overcome a prior judicial determination that sheer volume does not equate to adequate discovery.

This Court has now been presented with affidavits couched in the intentionally vague description of "discovery of some form or fashion" (Fujisawa, Sicor and Watson) or "some form of discovery" (Aventis) as to which drugs listed on "Exhibit B" were subject to discovery and produced in this matter. Specificity of drugs is realized only with Amgen (with 6 drugs listed on "Exhibit B") and Immunix (with 5 drugs listed on "Exhibit B"), each of which identifies the specific drugs in this case and attests that these drugs have been subject to discovery. No other Defendants make specific reference in their affidavits to *any* of the 85 newly added drugs by name -- not in the context of whether these Newly Added Drugs were in fact searched and produced in discovery (as required by the Commonwealth Court). Dey, however, does

acknowledge that each of its Subject Drugs, "except AccuNeb and Sodium Chloride" were included in Plaintiffs' definition of AWPIDs. These are two Newly Added Drugs. Therefore, the concession of a lack of discovery is welcome, but the silence of others is telling.

3. The Notice Previously Sent to Class 1 Consumers Has Been Shown to be Material Deficient in its Failure to Reached All Affected Medicare Beneficiaries.

Certain Named Plaintiffs object that the new notice must sent to all identifiable consumers in Classes 1 and 3 to cure the materially deficiencies in the original notice plan, in both its substance and the manner in which it was disseminated. New notice is required to advised consumers of the many, material changes to the proposed Track 2 settlement.

New notice must be sent by first class mail to all affected consumers whose names and addresses are known to Class Counsel – via the CMS and TPP databases – advising of the new proposed settlement. Such notice must be sent to all Medicare beneficiaries in Class 1 and identifiable consumers in Class 3, not just those limited purchasers of Group A drugs, since the subjective determinations of Class Counsel in splitting Track 2 drugs into Groups A and B was at best arbitrary, at worst, erroneous. Due process compels such notice. Because such new notice will be costly, the costs should be borne by Class Counsel and/or the Defendants, who have created the need for new notice by their material changes to the proposed settlement.

In *Phillips Petroleum Company v. Shutts*, 472 U.S. 797 (1985), the Supreme Court set forth the minimum procedural due process requirements necessary if *res judicata* is to bind an absent class action plaintiff:

> If the forum State wishes to bind an absent plaintiff concerning a claim for money damages or similar relief at law, it must provide minimal procedural due process protection. The plaintiff must receive notice plus an opportunity to be heard and participate in the litigation, ... The notice must be the best practicable, "reasonably calculated, under all the

> circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections." The notice should describe the action and the plaintiffs' rights in it. Additionally, we hold that due process requires at a minimum that an absent plaintiff be provided with an opportunity to remove himself from the class by executing and returning an "opt out" or "request for exclusion" form to the court. Finally, the Due Process Clause of course requires that the named plaintiff at all times adequately represent the interests of the absent class members.

Shutts, 472 U.S. at 811-12 (citations omitted).

In *Mullane v. Central Hanover Trust*, the Supreme Court stated that "[a]n elementary and fundamental requirement of due process in any proceeding which is to be accorded finality is notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections. … When notice is a person's due, process which is a mere gesture is not due process. The means employed must be such as one desirous of actually informing the absentee might reasonably adopt to accomplish it." 339 U.S. 306, 315 (1950). In that case, the Supreme Court held that publication notice is not sufficient under the Fourteenth Amendment for persons whose whereabouts are known, since it is not impracticable to make serious efforts to notify them at least by ordinary mail to their addresses on record. *Id.* Specifically, the Court held that "**[w]here the names and post office addresses of those affected by a proceeding are at hand, the reasons disappear for resort to means less likely than the mails to apprise them of its pendency**." *Id.*

In this case, Class Counsel sought to divert their constitutional obligations to tell all affected Class members about their rights in this case via first class mail notice. Throughout the majority of the pendency of this action, and the various settlement agreements presented to the

Court for approval, this Court agreed and endorsed the fundamental tenant that where the names and addresses of those to whom notice is required are readily available, as here, direct mail notice is notice reasonably calculated, under all the circumstances, to apprise the parties. *See e.g.* Dkt. Nos. 5132 (Class Counsel's Memo in Support of Preliminary Approval)(Specifying direct mail notice to all potential members of Class 1 utilizing data obtained from CMS), 5703 (Class Plaintiff's Report to The Court)(notifying the court that Class Counsel was still in the process of obtaining the CMS data needed for direct mail notice to all potential members of Class 1), 5754 (same), 6867 (CMS vender cooperating). Indeed, on January 4, 2011 this Court issued an Order specifically directing Class Counsel to proceed with direct mail notice to all potential members of Class 1 identified through the CMS data[13]. *See* Electronic Order, 1/4/2011.

In previous hearings on the Track 2 Settlement, this Court voiced serious concerns over implementing an expensive publication notice plan, when names and addresses of class members were readily available by which to disseminate direct mail notice. *See* March 14, 2008 Hrg Tr. at 23:4. In analyzing the proposed notice plan for this settlement, the court inquired about the previous success of "media blitz" in a prior settlement. The Court was told by Class Counsel that the class response to the media blitz "was not good" and "may have been one percent or less that are responses related to the publications." *Id.* at 22:20-23:2. Class Counsel estimated the cost of the media campaign to be "not much less than $2 million." *Id.* at 23:6. The Court, then concerned about maximizing the notice plan's "bang for the buck", *id.* at 23:7-8, inquired as to whether it would be more cost effective to use some of that money to defray the costs of further first class mail notice. The Court also made clear concerns at the time that the notice should be

[13] Notably, the CMS data identified 19.3 million individuals for whom Medicare made a payment. *See* Dkt. No. 7358, Class Plaintiff's Status Report For BMS, Track Two and AstraZeneca Settlements.

limited to only those people who are in the Class. *Id.* at 26:6-11 ("I want to know everything right now, so I'm not sending out notices to people and then I later find out that I may or may not agree with who's in the class.")

However, and notwithstanding all of the above, three days after this Court ordered direct mail notice to the entirety of the putative settlement Class that could be identified through the CMS data, on suggestion of Class Counsel and a later request by TPP allocation counsel and counsel for the ISHPs, *see* Dkt. Nos. 7367 and 7380, this Court abruptly compromised the constitutionally mandated class notice when it agreed to significantly limit notice to only 2.2 million of the 19.3 million potential members of the consumer Class. *See* Order, 1/7/2011.

Class Counsel noted that one reason for their not wanting to provide notice to all Class 1 consumers was that, "[m]ost Medicare recipients have supplemental insurance to cover their 20% co-insurance payment and do not pay this amount out-of-pocket and are therefore not class members." *See* Dkt. No. 7367 at p.3. They further claimed that "Dr. Hartman [had] estimated that approximately 15% of Medicare recipients do not carry some form of supplemental insurance" and that the notice of all Class 1 consumers identified in the CMS data was therefore over inclusive for "perhaps 4 out of 5 recipients of the notice." The ISHPs, for their part, citing to Dr. Hartman, identified the class as solely consisting of "consumers covered by Medicare who did not have supplemental insurance to cover their 20% co-insurance payment." *See* Dkt. No. 7380 n. 3. The ISHPs further complained that the expense of direct mail notice was too high and that the Court should endorse eliminating notice to the majority of the notice recipients. *See id* at pp.3,4.

On these representations, the Court agreed to severely limit Class 1 notice to provide direct mail to only purchasers of the 7 Group A drugs. *See id*. The rest of Class 1 consumers who purchased Group B drugs got the benefit of only publication notice, even though their names and addresses were well known. In view of the above, however, Class Counsel's subjective determinations about why drugs should be elevated to Group A status was erroneous as to at least the 22 single source brand drugs the Defendants now concede are in Group B, and Certain Named Plaintiffs argue should be in Group A, along with certain other brands.

Track 2 Defendants in this case are looking for an extraordinary release – broader than that afforded to any Track 1 Defendant. In Track 1 settlements with AstraZeneca and BMS, the CMS database was fully utilized to notify purchasers of branded PADs of their rights in this case. Respectfully, the Court should not corners in Track 2, most expansive and complex settlement of them all. Notice of the new proposed Settlement should be sent via first class mail to all settlement Class members. *See Whitford v. First Nationwide Bank*, 147 F.R.D. 135, 139 (W.D.Ky.,1992) ("Because the names and last known addresses of all class members were available from the defendant's business records, the mailing of the notice of the proposed settlement agreement and the fairness hearing was the best notice practical under the circumstances.") (*Citing Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 315 (1950)). Only by employing full use of the CMS and TPP databases to notify all identifiable consumers of their rights can the Court begin to cure the problems created by Class Counsel's belated acknowledgement that their prior settlement assumptions were wrong. The need to re-notice all Medicare beneficiaries is also underscored by the fact that now Class Counsel are imposing additional requirements on participation in the settlement Class. For instance, consumers who received "not otherwise classified" drugs now must "present some documentary

proof that they were administered a Track Two drug before receiving any compensation in the Settlement." Suppl Submission at 16-17. Further, since $1.9 million in settlement proceeds is being stripped from Epogen purchasers, like Rev. Aaronson, the consumers in both Classes 1 and 3 need to be told so that they can lodge any objections they have to an insulting $5 paid as "consideration for providing a release." *Id*. at 15.

II CONCLUSION

For the foregoing reasons, we object and ask that the proposed Track 2 consumer settlement classes not be certified and that the proposed Track 2 settlement be rejected.

Dated: August 5, 2011

Respectfully submitted,

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr., Esquire
Robert G. Hughes, Esquire
Michael J. Lorusso, Esquire
HAVILAND HUGHES, L.L.C.
111 S. Independence Mall East
The Bourse, Suite 1000
Philadelphia, PA 19106
Telephone: (215) 609-4661
Facsimile: (215) 392-4400
Counsel for Certain Named Plaintiffs, Rev. David Aaronson, Katie Bean (for Harold Bean), Jimmie May Carter (for Harold Carter), Roger Clark, Rebecca Hopkins, Joyce Howe, Pat Drewett (for James Monk), Virginia Newell, Oral Roots, Mary Wright (for James Shepley), Beverly Thomson Shaw, Esq. (for George Baker Thomson), Ethel Walters, and Larry Young

CERTIFICATE OF SERVICE

I, Donald E. Haviland, Jr., hereby certify that on August 5, 2011 the foregoing Certain Named Plaintiffs' Objections to Plaintiffs' Supplemental Submission in Support of Rebalanced Track Two Settlement was filed via CM/ECF and all counsel of record were served via ECF notification.

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr.